

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION**

**UNITED STATES OF AMERICA *ex rel.*
JEFFREY H. LIEBMAN and DAVID M.
STERN, M.D.**

Plaintiff,

v.

**METHODIST LE BONHEUR
HEALTHCARE, METHODIST
HEALTHCARE-MEMPHIS HOSPITALS,**

Defendants.

Case No. 3:17-CV-00902

**District Judge William L.
Campbell, Jr.**

**Magistrate Judge Barbara D.
Holmes**

**DEFENDANTS' REPLY MEMORANDUM IN SUPPORT OF MOTION FOR
SUMMARY JUDGMENT**

BASS, BERRY & SIMS PLC

Brian D. Roark

J. Taylor Chenery

Taylor M. Sample

Hannah E. Webber

BASS, BERRY & SIMS PLC

150 Third Avenue South, Suite 2800

Nashville, TN 37201

AKIN GUMP STRAUSS HAUER & FELD LLP

Robert S. Salcido

(Admitted Pro Hac Vice)

2001 K Street, N.W.

Washington, DC 20006

*Attorneys for Defendants Methodist Le
Bonheur Healthcare and Methodist
Healthcare-Memphis Hospitals*

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I. INTRODUCTION

The government must present concrete admissible evidence to establish a triable issue of fact as to False Claims Act (“FCA”) causation, falsity, and scienter, but fails to present any such evidence as to any of these elements.

As to causation, notwithstanding that this litigation is in its sixth year, that the government’s complaint is the fifth iteration of alleged facts, and that Methodist has responded to more than 70 document requests and interrogatories from the government, responded to more than 180 document requests from Relators and produced more than 180,000 pages of documents (*see* Dkt. No. 341 at 2, describing productions), the government does not satisfy this circuit’s but-for causation standard because the government points to *no evidence* of any link between a specific physician (or any subset of physicians or list of sampled physicians) and a specific kickback that that physician allegedly received, and then to a specific referral that resulted from the specific kickback. The government does not establish what compensation was paid to any specific West physician, whether the compensation paid to that physician exceeded fair market value (“FMV”), or whether any referrals from that physician resulted from improper payments.

As to falsity, the government does not present any summary judgment evidence that Methodist made any false certification of compliance with the Anti-Kickback Statute (“AKS”) because (i) there was no violation under the AKS because the only undisputed summary judgment evidence is that all payments were at FMV and hence, as a matter of law, were not remuneration under the AKS and (ii) Methodist’s opinion that it complied with the AKS was not objectively false because it was founded upon its belief that it complied with the law based upon obtaining contemporaneous opinions from experts, and all that exists ultimately is a disagreement among testifying experts regarding whether contemporaneous FMV methodologies were sound.

As to knowledge, the government does not submit concrete evidence showing that any person at Methodist knowingly and willfully, at any point in time, through specific conduct sought to, or actually did pay, a kickback to any individual at West. Therefore, the Court should grant Methodist's summary judgment motion.

II. THE GOVERNMENT DOES NOT ESTABLISH FCA / AKS CAUSATION

The government contends that it has satisfied this circuit's but-for causation standard because the but-for causation rule enacted in 2010 does not apply to what is undisputedly post-2010 conduct. (*See* Dkt. No. 345 at 18.) The government's position conflicts with the plain language of the statute and controlling Sixth Circuit precedent. The government raised this position previously before the Sixth Circuit, and the Sixth Circuit rejected it. Because the government cannot demonstrate but-for causation with any non-speculative summary judgment evidence, its action should be dismissed.

A. The Government Must Satisfy the But-For Causation Standard

The government contends that it does not need to establish but-for causation because it can simply establish "an FCA violation predicated on kickbacks" based upon "the well-established FCA caselaw that existed before the 2010 Amendments to the AKS[.]" (*Id.* at 18.) This position is inconsistent with the AKS's plain language and controlling Sixth Circuit precedent. Moreover, the government raised this very argument in *Martin*, and the Sixth Circuit rejected it.

First, the AKS's causation standard provides the only means to establish an AKS violation in an FCA action. In 2010, Congress amended the AKS to define precisely when an AKS violation could result in a "false or fraudulent" claim under the FCA. 42 U.S.C. § 1320a-7b(g). The AKS provides that "a claim that includes items or services *resulting from* a violation of [the AKS] *constitutes a false or fraudulent claim* for purposes of [the FCA]." *Id.* (emphasis added). As the Sixth Circuit recently observed, "[w]hen it comes to violations of the [AKS], *only* submitted claims 'resulting from' the violation are covered by the [FCA]" and the "ordinary meaning of 'resulting

from’ is but-for causation.” *U.S. ex rel. Martin v. Hathaway*, 63 F.4th 1043 (6th Cir. 2023). That is, § 1320a-7b(g) provides the exclusive means to establish an AKS violation under the FCA. There is no alternative statutory provision that defines when claims are “false or fraudulent” under the FCA when alleging an AKS violation.

Second, in *Martin*, the Sixth Circuit *expressly rejected* this very argument now urged by the government that pre-2010 false certification case law meant that plaintiffs alleging an AKS violation in an FCA case could dispense with establishing a causal link:

The government argued that several pre-2010 false certification cases did not require a causal link between the kickback scheme and the claim presented. As the government saw it, the 2010 statutory amendment had “simply codified” the holdings of those cases. [*U.S. ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 836] (quotation omitted). The Eighth Circuit responded that Congress could have codified those cases by using language that did so. *Id.* “[T]ainted by” or “provided in violation of,” for example, would have set out an alternative causation standard. *Id.* But Congress used “resulting from,” an “unambiguously causal” standard even in the face of these pre-amendment cases. *Id.* Where a statute “yields a clear answer, judges must stop.” *Food Mktg. Inst. v. Argus Leader Media*, ...139 S. Ct. 2356, 2364, 204 L.Ed.2d 742 (2019).¹

B. The Government Has Not Satisfied this Circuit’s But-For Causation Test

As a back-up plan, the government asserts that the but-for standard applied in *Martin* is satisfied because in *Martin*, “the alleged scheme did not change anything”; thus, the government reasons, as long as it shows that something did change, it satisfies but-for causation. (*See* Dkt. No. 345 at 22-23.) That argument misinterprets the but-for standard, and the Sixth Circuit has

¹ *Id.* at 1053. In its amicus brief, the government noted that FCA liability could be found multiple ways, including, as the government asserts here, through a false certification theory. *See* Brief of Amicus Department of Justice (“Amicus Br.”) at 4, *Martin*, 63 F.4th. at 1052. But the Sixth Circuit ruled that when it comes to the AKS, *only* submitted claims resulting from the violation *are covered* by the FCA. *Martin*, 63 F.4th at 1052. Thus, the government is wrong that this issue was not addressed in *Martin*. To the extent the government relies on the out-of-district unpublished district court case in *United States v. Cameron-Ehlen Grp. Inc.*, 2023 WL 36174, at *3 (D. Minn. Jan. 4, 2023), that decision is inconsistent with the plain language of the statute and with *Martin*.

expressly rejected it. Under Supreme Court and Sixth Circuit precedent, the government must provide concrete, non-speculative summary judgment evidence that the physician referral occurred because of—i.e., *resulted from*—the payment of the kickback. *See Burrage v. United States*, 571 U.S. 204, 210-11 (2014); *Martin*, 63 F.4th at 1053-54. As *Martin* makes clear, Congress, in selecting the “resulting from” mandate, worked from “the backdrop of a handful of cases that observed similar language as requiring but-for causation.” *Martin*, 63 F.4th at 1052. “[T]he phrase ‘results from’ is not ambiguous.” *United States v. Jeffries*, 958 F.3d 517, 521 (6th Cir. 2020). In *Burrage*, the Court held that to demonstrate that one thing “results from” another “requires proof that the harm would not have occurred [i.e., presentation of a false claim] in the absence of—that is, but for—the defendant’s conduct [i.e., payment of a kickback].” 571 U.S. at 211 (internal citation and quotation marks omitted); *see also Cairns*, 42 F.4th at 834 (holding that “the government had to prove here that the defendants would not have included particular ‘items or services’ absent the illegal kickbacks,” and that but-for causation “is an ‘essential element’ [of AKS / FCA liability] that must be proven, not presumed”).

In adopting this standard, the Sixth Circuit held that *even at the pleading stage*, a plaintiff must allege sufficient facts anchoring, in time and place, the specific referral to the specific kickback. 63 F.4th at 1053-54. To determine whether the plaintiff could satisfy but-for causation, the Sixth Circuit examined, on a claim-by-claim basis, each of 14 different referrals that the plaintiff contended violated the AKS. In examining the plaintiff’s allegation that a physician made an unlawful referral because it was made seven months after the alleged unlawful agreement, the Sixth Circuit ruled that the plaintiff could not establish but-for causation because mere “[t]emporal proximity by itself does not show causation,” and there was no “identifiable exchange of value” between the hospital and the specific physician “to anchor the scheme in time or place.” *Id.*

Methodist, in its summary judgment motion, identified testimony from three West physicians whom the government deposed and five West physicians who provided declarations, who provided bona fide, detailed explanations for why they increased referrals to Methodist during the time the parties operated a cancer center. (*See* Dkt. No. 321 at 18 – 21.) They uniformly testified that they referred patients to Methodist (or other hospitals) based on the patients’ best interests and that no payment from Methodist to West influenced any referral decisions. (*Id.*) In its opposition, the government does not rebut the physicians’ testimony with *any* contrary evidence. (*See, e.g.*, Dkt. No. 346, United States’ Resp. to Statement of Undisputed Material Fact ¶ 179). The government offers no proof from any other West physician or witness that any referral from any physician resulted from a kickback. Instead, the most the government can do is identify a provision of the PSA that West physicians “shall use their best efforts to utilize” Methodist services for patient treatment and to argue this is an “explicit causal link to the referrals.” (Dkt. No. 345 at 24.) This in no way establishes causation. Such “direct referral” provisions in PSAs are permitted by law.² Moreover, the government never bothered to ask any Methodist or West witness about this contractual provision, so it developed no evidence regarding how the provision was implemented or enforced, even though it argues the parties routinely disregarded their contractual obligations.

Further, aside from not satisfying *Martin*’s standard, the government’s assertions actually *disprove* but-for causation, not support it. The government contends it has demonstrated causation because West’s referrals to Methodist rose during the affiliation then dropped after it ended, and

² Rather than being unlawful, or even wrongful, directed referrals are permitted by law regarding PSAs. *See* 42 C.F.R. § 411.354(d)(4). As forecasted here, one can easily, and lawfully, anticipate that revenue will increase as a result of entering into lawful PSAs. Rather than constituting proof of unlawful behavior, it is simply proof of lawful and appropriate behavior.

certain West providers increased referrals to Methodist while decreasing referrals to Baptist. (See Dkt. No. 345 at 24.) This contention is based solely on an analysis that found that only eight of 86 West physicians increased referrals to Methodist while decreasing referrals to Baptist. (See Dkt. No. 347 ¶¶ 9, 11.) This analysis, involving fewer than 10% of West’s physicians, in fact *undermines* the entire premise of the government’s causation argument and further illustrates why the Court should grant Methodist’s motion.³

The government knows exactly what but-for causation requires under the AKS/FCA. In *Martin*, the government urged the Sixth Circuit *not* to adopt the but-for causation standard because if courts applied such a standard, it “would significantly complicate the litigation of FCA cases based on AKS violations, *requiring extensive efforts to disentangle the motivations of treating physicians* (who may not even be among the defendants) *for every treatment decision or referral at issue* (often numbering in the hundreds or thousands).” Amicus Br. at 22 (emphasis added). That has now come to fruition. But here, the government never even attempted any “disentangling” that it, itself, understood would be required were the Sixth Circuit to (as it did) adopt a but-for causation standard. In short, the government’s case is a complete failure of proof.⁴

³ Although this analysis actually supports Methodist’s motion, there are two reasons the Court should give it no weight. First, the analysis was submitted as part of Michael Petron’s declaration, but, as is set forth in a motion to exclude, the government failed to disclose Petron as an expert and provided no evidentiary foundation for the Medicare claims data Petron purports to analyze. Second, it asks the Court to infer causation based solely on the fact that some West physicians made referrals after West entered into an affiliation with Methodist. But causation “must be proven, not presumed.” *Cairns*, 42 F.4th at 835. *Martin* expressly rejected that a referral made after an agreement is entered is sufficient to prove but-for causation. See 63 F.4th at 1053-54.

⁴ Recognizing that its assertion that all physician referrals were the but-for cause of kickbacks is nothing more than rank speculation, the government argues Methodist is wrong to state that the government’s case cannot depend on speculation. (See Dkt. No. 345 at 24.) But this circuit has consistently required plaintiffs to establish the entire causal chain constituting an FCA violation, from the alleged violation to the actual claim, through non-speculative facts—even at the *pleading stage*, let alone at summary judgment after years of discovery. See *U.S. ex rel. Ibanez v. Bristol-*

III. THE GOVERNMENT DOES NOT ESTABLISH FCA FALSITY

The only admissible evidence is that during the arrangement, Methodist and West exchanged FMV. (*See* Dkt. No. 321 at 24.) Because, under the AKS, FMV payments are not remuneration, there is no AKS violation, and, hence, no FCA violation as a matter of law. But even if remuneration were paid, there is no FCA falsity because Methodist had a reasonable opinion that the arrangement was FMV and thus did not submit any objectively false certification.

A. The Government Does Not Establish the Payment of AKS Remuneration

The government does not submit any admissible evidence that remuneration was paid. As Methodist previously noted, the Sixth Circuit has twice stated that one of the reasons remuneration in the AKS is limited to “transfers . . . for free or for other than fair market value” is because that is how a related civil statute, the Civil Monetary Penalty Law (“CMPL”), 42 U.S.C. § 1320a-7a(i)(6), defines remuneration. (*See* Dkt. No. 321 at 11.) Applying this definition, Methodist pointed out that it must prevail because the only undisputed evidence is that the payments made under the arrangements were FMV, even taking into account perceived errors, which Methodist denies. (*See id.* at 24.)

But the government contends that *Martin*, which specifically rejected the government’s proffered definition of remuneration, somehow, *sub silentio*, reversed the Sixth Circuit’s statements in *Miller* and *Jones-McNamara v. Holzer Health Sys.*, 630 F. App’x 394 (6th Cir. 2015), regarding the meaning of remuneration. The government states that in *Martin*, “the Sixth Circuit did *not* hold that the CMPL definition of remuneration applies to the AKS, and the Court instead held that ‘remuneration’ under the AKS covers ‘payments and other transfers of value.’” (Dkt.

Meyers Squibb Co., 874 F.3d 905, 914 (6th Cir. 2017) (“Rule 9(b) requires relators to adequately allege the entire chain—from start to finish—to fairly show defendants caused false claims to be filed”); *Miller v. Abbott Labs.*, 648 F. App’x 555, 562 (6th Cir. 2016) (finding when FCA suit alleges AKS violation, allegedly false claims must be “link[ed]” to the asserted kickback).

No. 345 at 11-12.) The government’s conclusion is mistaken. The Sixth Circuit’s express holding in *Martin* did not directly address whether FMV payments are remuneration, but, given that the Sixth Circuit applied the same statutory analysis as it had in *Miller* and *Jones-McNamara*, its analysis in *Martin* indicates that it would in fact reach the same conclusion that remuneration does not include FMV payments.

First, the common denominator in circuit court decisions regarding this issue is that they use the definition of the AKS’s statutory “cousin,” the CMPL, to interpret what “remuneration” means. Specifically, the Eleventh Circuit in *Bingham v. HCA, Inc.*, 783 F. App’x 868 (11th Cir. 2019), and this circuit in *Miller* and *Jones-McNamara* have looked to the CMPL’s definition of remuneration—that it includes “*transfers of items or services for free or for other than fair market value*,” 42 U.S.C. § 1320a-7a(i)(6) (emphasis added)—and applied that same definition of remuneration under the AKS. In *Martin*, the Sixth Circuit did precisely the same thing. It looked to the CMPL’s definition of remuneration, which expressly includes the word “transfers,” in concluding that remuneration under the AKS requires transfers of value. There is no reason to believe that the Sixth Circuit used the first part of the CMPL definition but would have rejected using the remaining portion—“. . . for free or for *other than fair market value*”—to interpret remuneration under the AKS. *See Martin*, 63 F.4th at 1049.⁵ As Methodist pointed out, this Court

⁵ The Sixth Circuit’s overt reliance on 42 U.S.C. § 1320a-7a(i)(6) to construe “remuneration” under the AKS, its statutory cousin, was not done blindly or in error. In its amicus brief in *Martin*, the government expressly informed the Sixth Circuit that it believed the panels in *Miller* and *Jones-McNamara* committed “error” in construing the scope of remuneration in the AKS based upon the CMPL definition. *See* Amicus Br. at 12 & n.1. Yet the Sixth Circuit then proceeded to do exactly what the government characterized as “error”: using the CMPL statutory definition to construe “remuneration” under the AKS. The court should do the same as the Sixth Circuit did in *Miller*, *Jones-McNamara*, and *Martin* here in construing the meaning of remuneration in the AKS. Because remuneration is “transfers . . . for free or for other than fair market value,” the court should dismiss the government’s complaint for failure to show any non-FMV payments were made.

should do exactly as the Sixth Circuit did in *Martin*, *Miller*, and *Jones-McNamara*: use the definition of “remuneration” at 42 U.S.C. § 1320a-7a(i)(6) to construe “remuneration” for purposes of the criminal AKS. It is extremely implausible that Congress intended to create a lower threshold for proving remuneration under the *criminal* AKS than under the *civil* CMPL. And it is imminently reasonable that paying a doctor FMV does not provide the basis for a criminal kickback scheme. This action should be dismissed because the only summary judgment evidence is that FMV was paid. (*See* Dkt. No. 321 at 24.)

Although the government argues it is not required to show payments from Methodist to West were not FMV, it submits that there is still “ample evidence” by which “a reasonable jury could conclude that the value of Methodist’s payments to West exceeded FMV.” (Dkt. No. 345 at 14.) The government’s primary argument is that the contemporaneous valuations obtained by Methodist and West at the time of the arrangement are not reliable because the valuations were based on erroneous assumptions and were the product of opinion shopping, and that the parties’ agreements were not implemented consistently with the opinions. (*Id.* at 14–15.)

The fatal flaw in the government’s rationale is that questioning the reliability of FMV opinions does not constitute affirmative proof that any payments made were not FMV. If a hospital agreed to pay a doctor \$100 for services, questioning the validity of the hospital’s FMV opinion would not constitute evidence that \$100 was above FMV. The government would need evidence of what services the doctor performed and what FMV was for those services. The government offers no such proof here. Although the government retained Tim Smith, a valuation expert, he expressly disclaimed that he was providing any FMV opinion. (*See* Dkt. No. 346 ¶ 211). Smith criticized the contemporaneous opinions Methodist obtained, but he did not determine what FMV *should have been*. (*Id.*) Indeed, neither the FCA nor AKS requires FMV opinions at all.

For the MSA, Methodist supports its motion by identifying voluminous evidence of the specific management services West provided and the outcomes attained through those services. The government argues that this proof is not relevant but does not otherwise rebut it because it cannot. The government notes that Methodist paid West \$24,689,770 over the MSA’s seven-year term, but offers no proof— through testimony, documents, or otherwise—that the FMV of those services was some amount lower than what Methodist paid. Similarly, with the PSA, Smith conducted no analysis and provided no testimony about what the FMV of those services was or that Methodist paid West an amount lower than FMV.

On the other hand, Methodist’s expert Todd Mello conducted a retrospective analysis concluding that the amounts Methodist paid to West were FMV. (Dkt. No. 322 ¶¶ 46-47.) The government makes conclusory claims that Mello “failed to consider all the known information” and “provided meaningless opinions,” (Dkt. No. 345 at 14), but the government chose not to offer its own expert to rebut Mello’s testimony. The government cites *Kuzma v. Northern Arizona Healthcare Corp.*, 607 F. Supp. 3d 942, 948 (D. Ariz. 2022), for the proposition that having Smith criticize the underlying FMV opinions is enough to prevent summary judgment. Not so. Even in this out-of-circuit case applying a different legal standard than what controls here, the court still found that the relator/CFO had put forward a competing valuation that constituted some affirmative proof on the plaintiff’s part.⁶ On the record before the Court here, the government has offered no countervailing proof as to FMV.⁷ (Dkt. No. 346 ¶ 211 (acknowledging that “the United

⁶ The Arizona district court in *Kuzma* was applying a standard from a 20-year-old Northern District of Illinois decision, which, unlike the standard articulated by the Eleventh Circuit in 2019, did not place the burden of proof for FMV on the plaintiff. *Compare Kuzma*, 607 F. Supp. 3d at 947–49, *with Bingham*, 783 F. App’x at 873.

⁷ Finally, to the extent the government seeks to avoid summary judgment by raising unsubstantiated allegations about Methodist not charging West rent, not recouping “meaningful

States did not put forth any opinion on what the fair market value would be for the services under the various agreements”).

B. The Government Does Not Establish an Objective Falsehood

Even if the Court were to find that FMV payments are remuneration under the AKS, the government’s complaint should be dismissed because Methodist’s opinion that its practices complied with law—based upon the work of FMV consultants—is not objectively false.

As Methodist pointed out, statements of opinion—such as that the arrangement complies with the AKS because every component was within FMV—are not actionable under the FCA because the FCA applies only to objective falsehoods. (*See* Dkt. No. 321 at 29 (citing five circuit opinions)). While the government never conducted a retrospective FMV analysis, even if all that existed were a debate between the government’s expert, Smith, who believes the FMV experts used flawed methodologies, and Methodist’s expert, Mello, who concluded these methodologies were reasonable, there is no FCA liability because reasonable disagreement among experts does not constitute fraud. *Id.*

The government, without citing contrary circuit authority, argues that these five circuit courts’ rulings should be ignored because the Sixth Circuit has not yet addressed the issue and because none of them concerned the AKS.⁸ (*See* Dkt. No. 345 at 17.) These courts’ uniform

use” payments, allowing West to hold itself out as West Cancer Center, or paying for employees who also did work for West, these allegations fail. First, as noted, the only summary judgment evidence is that even taking into account perceived errors, all payments were at FMV. (*See* Dkt. No. 321 at 24.) Second, in any event, the government has not, at the summary judgment stage, developed specific proof with competent evidence to support any of these contentions. *See Emerson v. Novartis Pharms. Corp.*, 446 F. App’x 733, 736 (6th Cir. 2011) (“A district court is not required to search the entire record to establish that it is bereft of a genuine issue of material fact. Judges are not like pigs, hunting for truffles that might be buried in the record.”) (citations omitted). As such, it has failed to carry its burden of proof, and its claims should be dismissed.

⁸ Oddly, citing *U.S. ex rel. Odom v. Southeast Eye Specialists, PLLC* (“SEES”), 570 F. Supp. 3d 561, 575 (M.D. Tenn. 2021), the government seems to indicate that the objective falsity doctrine

reasoning correctly defines the scope of what constitutes fraud based on common law principles that the FCA incorporates.⁹ The government is wrong that a court would be less inclined to apply objective falsity in an AKS action. Indeed, as found in *Martin*, a court would be more inclined to apply it to a criminal statute because of the principle of lenity. *See* 63 F.4th at 1050.

IV. THE GOVERNMENT HAS NOT ESTABLISHED FCA / AKS SCIENTER

There is insufficient summary judgment evidence to find Methodist acted knowingly and willfully because the government's assertions do not satisfy the AKS's knowing and willful element based on the summary judgment record.¹⁰

To establish that an AKS defendant acted knowingly and willfully, the government must show the defendant knew that its conduct was wrongful. (*See* Dkt. No. 321 at 32 (citing cases).) The government does not set forth any evidence creating a genuine dispute of fact that anyone at Methodist engaged in knowing and willful misconduct. Indeed, the only evidence the government points to is

cannot apply because the government is pursuing a “legally false” express false certification theory (i.e., Methodist allegedly falsely certified compliance with the AKS when, allegedly, it did not comply with the AKS). (*See* Dkt. No. 345 at 17.) But there is no such exception to the doctrine. Courts have applied the doctrine when what is alleged, like here, is the submission of a false certification. *See, e.g., Bell v. Cross*, 2021 WL 5544685 (11th Cir. Nov. 26, 2021); *United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019). There is nothing in *SEES* stating otherwise.

⁹ *See, e.g., AseraCare*, 938 F.3d at 1297 (applying common law principles regarding when statements of opinion may be false).

¹⁰ In Methodist's initial brief, Methodist invoked the FCA's reasonable interpretation of ambiguous law doctrine as a defense. Specifically, Methodist raised this argument at Dkt. No. 321, in three paragraphs, starting with the second full paragraph at page 30, but excluding note 17. Based upon the Supreme Court's ruling in *U.S. ex rel. Schutte v. Supervalu Inc.*, No. 21-1326 (June 1, 2023), Methodist withdraws the argument in these three paragraphs exclusive of note 17. The Supreme Court's decision impacts solely this issue. *See id.* at 7-8 (underscoring that the issue the Court reviewed raised “one discrete legal issue” and the Court resolves “only that issue,” which was that defendants could have the scienter required by the FCA if they correctly interpreted the relevant standard and knew their claims were false). The Court's resolution of this narrow issue does not impact any other argument Methodist raised, each of which separately results in the dismissal of the government's action.

permitted under the law, and hence the government fails to set forth sufficient evidence to establish that Methodist acted knowingly and willfully.¹¹

The government asserts that it creates a genuine issue of material fact as to FCA/AKS scienter because: (i) “one purpose” of the affiliation was to induce referrals from West to Methodist for inpatient and outpatient services through the conversion of West’s outpatient locations to Methodist outpatient departments; (ii) the parties sought to achieve cost savings through the 340B Discount Drug Program; (iii) some West physicians were paid above the 90th percentile; and (iv) West tracked patient referrals. (*See* Dkt. No. 345 at 28-29.)

But, far from describing criminal conduct, each of these alleged acts have been found in public pronouncements to be consistent with law. *First*, as noted, entering into a PSA and directing referrals is anticipated and encouraged by law; it therefore cannot constitute a violation of law. *See* 42 C.F.R. § 411.354(d)(4). *Second*, as the Supreme Court has stated, the 340B program was intended to benefit hospitals like Methodist that perform valuable services for low-income beneficiaries and have to rely on limited federal funding, and, as 340B hospitals have pointed out, Congress expressly intended for 340B discounts to subsidize other services provided by 340B hospitals, including cancer treatment. *See AHA v. Becerra*, 142 S.Ct. 1896, 1901 (2022). *Third*, as a district court in this circuit has recognized, there is nothing unlawful about physicians being paid at or above the 90th percentile,¹² and the government has not tendered any FMV analysis at

¹¹ Even at the pleading stage, let alone at summary judgment, courts routinely rule that if there is an alternative lawful explanation for defendant’s behavior and plaintiff does not offer something more to exclude the possibility that the alternative explanation is true, plaintiff does not state a plausible claim for relief under the FCA. *See, e.g., U.S. ex rel. Sibley v. Univ. of Chi. Med. Ctr.*, 44 F.4th 646, 660 (7th Cir. 2022) (affirming dismissal when plaintiff’s complaint pleads facts “merely consistent with” defendant’s FCA liability).

¹² *See, e.g., U.S. ex rel. Villafane v. Solinger*, 543 F. Supp. 2d 678, 691-92 (W.D. Ky. 2008) (rejecting relator’s contention that payment at 90th percentile and 75th percentile were inherently above FMV and hence violated the Stark law requiring FMV payments, noting that each doctor

summary judgment demonstrating that any particular West physician received an above-FMV payment for services furnished under the PSA. To the contrary, the only FMV analysis in the record reveals that West earned less under the PSA than it had been earning in independent practice prior to the affiliation. (Dkt. No. 322 ¶ 47.) *Fourth*, as other district courts have ruled, there is nothing criminal about health care providers tracking referrals; indeed, far from being a crime, as the government asserts, this is a prudent business practice.¹³

The government also argues that there is evidence of knowing and willful scienter because of “Methodist’s knowledge of the AKS, manipulation of fair market value opinions, disregard for contractual obligations, letting West decide performance incentives, and failing to do any real compliance surrounding the deal.” None of these allegations constitutes proof of scienter. First, the government provides no specific factual citations regarding “Methodist’s knowledge of the AKS” nor explains what this means. Second, although the government’s expert did identify alleged errors in FMV opinions, the government cites to no testimony or evidence that Methodist “manipulated” the opinions or knew of the errors. Third, the government does not indicate how

“appears to be highly qualified and arguably at or near the top of his profession” and that relator’s expert’s findings “suggest only that Defendant physicians were paid at a level consistent with their abilities, not that they were paid at an unreasonably high level”).

¹³ Courts commonly reject the government’s notion that a mere desire to increase volume somehow equates to a violation of the AKS. *See e.g., United States v. Holland*, at 31 (N.D. Ga. Nov. 17, 2022) (previously filed at Dkt. No. 301-1). In *Holland*, the court observed that it “agrees with Defendants that discussions of patient volume do not demonstrate a willful violation of the AKS.” *Id.* at 30. Indeed, as the court pointed out, it is “common sense that a hospital administrator would want to know how many patients are likely to show up at a hospital on a given day (or over a given period) for numerous reasons that have nothing to do violating the AKS.” *Id.* at 30. The court concluded that “hospital administrators have ample, legal reasons to monitor patient volume, and as a result the discussions, standing alone, do not establish that payments under the agreements were for something more than the value of the services provided.” *Id.* at 31. The court observed that standing alone the fact that defendants “have asked—or even badgered—the [clinic] to refer more patients is not an AKS violation.” *Id.* at 32.

disregarding contractual obligations or allowing West to set performance incentives, which are not supported by competent evidence, would constitute knowledge of an AKS violation. Fourth, the government does not identify any compliance function required by law that Methodist failed to perform or indicate how not performing compliance amounted to a knowing violation of the AKS.

Finally, the government has failed to show that Methodist, through any authorized employee, knowingly and willfully violated the AKS. The government argues that it has established vicarious liability under the FCA through Methodist's "top officers and employees like the CEO and CFO." (Dkt. No. 345 at 32.) Relators had alleged that Methodist's former CEO, Gary Shorb, and former CFO, Chris McLean, violated the AKS in prior versions of the complaint. However, when the government intervened, it dropped all claims against Shorb and McLean. The government's opposition brief makes no mention of Shorb, and, thus, no actions or knowledge on his part can establish scienter as to Methodist. As to McLean, the government notes that Relator Stern states that McLean told him that Methodist chose to partner with West in order to direct patients away from Baptist, McLean received referral tracking information from West in 2012, and McLean forecast that the deal could bring \$120 million in revenues from West's referrals. (*Id.* at 6.) Again, none of these contentions are sufficient to establish proof that Methodist knowingly and willfully violated the law from 2012-18.

Even assuming the government's facts were accurate, the government lacks sufficient summary judgment evidence to assert that Methodist acted with AKS scienter. Therefore, Methodist did not violate the FCA because it did not falsely certify compliance with the AKS.

V. CONCLUSION

For the foregoing reasons, Methodist's summary judgment motion should be granted.

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Respectfully submitted,

/s/ Brian D. Roark

Brian D. Roark
J. Taylor Chenery
Taylor M. Sample
Hannah E. Webber
BASS, BERRY & SIMS PLC
150 Third Avenue South, Suite 2800
Nashville, TN 37201
Telephone (615) 742-6200
Facsimile (615) 742-6293
broark@bassberry.com
tchenery@bassberry.com
taylor.sample@bassberry.com
hannah.webber@bassberry.com

Robert S. Salcido
(Admitted *Pro Hac Vice*)
Akin Gump Strauss Hauer & Feld LLP
2001 K Street, N.W.
Washington, DC 20006
(202) 887-4095
rsalcido@akingump.com

CERTIFICATE OF SERVICE

I hereby certify that a true and exact copy of the foregoing has been served on the following counsel via the Court's CM/ECF email notification system on this the 2nd day of June, 2023:

Bryan A. Vroon
Law Offices of Bryan A. Vroon, LLC
1766 West Paces Ferry Road
Atlanta, GA 30327
(404) 441-9806
bryanvroon@gmail.com

Jerry E. Martin
Seth Marcus Hyatt
Barrett Johnston Martin & Garrison, LLC
Philips Plaza
414 Union Street, Suite 900
Nashville, TN 37219
(615) 244-2202
jmartin@barrettjohnston.com
shyatt@barrettjohnston.com

Edward D. Robertson, Jr.
Bartimus Frickleton Robertson Rader PC
109 B East High Street
Jefferson City, MO 65101
(573) 659-4454
crobertson@bflawfirm.com

Kara F. Sweet
Wynn M. Shuford
Ellen B. McIntyre
U.S. Attorney's Office
Middle District of Tennessee
719 Church Street
Suite 3300
Nashville, TN 37203
(615) 401-6598
kara.sweet@usdoj.gov
wynn.shuford@usdoj.gov
ellen.bowden2@usdoj.gov

/s/ Brian D. Roark